DEPARTMENT OF HEALTH AND MENTAL HYGIENE
MARYLAND AIDS ADMINISTRATION
and
LABORATORIES ADMINISTRATION

PROTOCOLS
for
HIV Counseling and Testing

Using the OraQuick ADVANCE® testing system

November 2004

OraQuick ADVANCE® Policies and Procedures

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Overview:

Rapid testing for HIV has promise for increasing access to and acceptability of HIV testing among at-risk populations. This is achieved by helping to further reduce or remove barriers associated with traditional methods of testing. Increasing access and acceptability can facilitate provision of medical and supportive services to HIV infected individuals earlier in the course of infection. Application of this technology will also broaden our ability to identify at-risk individuals who are HIV negative. They could benefit from education and counseling to assist them in remaining uninfected.

The OraQuick® ADVANCE® Rapid HIV-1/HIV-2 Antibody Test provides results with 99% accuracy in as little as 20 minutes. Using oral fluid or a drop of blood, the OraQuick® ADVANCE® device can quickly and reliably detect antibodies for HIV-1and HIV-2. Oral fluid collection may make HIV testing more acceptable to clients who are afraid of veinipuncture techniques or who are venous compromised.

The simplicity of this test will allow OraQuick® ADVANCE® to be used more easily in non-clinical settings where individuals may not be trained in phlebotomy and where infrastructure does not allow for handling and/or storage of blood specimens. This simple test, that uses oral fluid or whole blood, eliminates the need for preparation of the sample through use of specialized equipment. OraQuick® ADVANCE® can be used by a wide variety of agencies, including non-traditional providers of HIV counseling, testing and referral (CTR) services. It can also be used in conjunction with outreach and field services (e.g., mobile van outreach).

The convenience of this test is designed to fulfill three main purposes. First, to encourage individuals to get tested for HIV who may not have thought of or agreed to being tested before. Second, to increase the number of people who learn their HIV status. Third, to decrease the need for follow-up activities to locate clients who do not return for their HIV test results. These factors combined may help to prevent the spread

of HIV, ensure the immediate access to services and/or treatment for those who are infected and reduce the amount of time associated with HIV CTR follow-up.

OraQuick ADVANCE® may also prove useful for pregnant women and for health professionals. The American Foundation for AIDS Research states that nearly 20% of all pregnant women do not know their HIV status at the time of delivery. OraQuick ADVANCE® would allow results to be obtained and treatment started if needed while the mother was still in labor. This action could substantially reduce the chance that the infant will become infected with HIV.

Additionally, many health care professionals experience accidental "needle sticks" every year. After a possible exposure, the use of a rapid test on a consenting client and the receipt of a negative test result may eliminate the practice of placing workers on post-exposure prophylactic medications unnecessarily.

Applications:

OraQuick ADVANCE® is primarily intended for use in CTR outreach programs targeting high-risk populations outside traditional health department clinics. It is more difficult to provide testing in these settings which include local detention centers or addictions clinics. In general, OraQuick ADVANCE® should not replace blood serum testing in LHD facilities and clinics where phlebotomy services are readily available, and blood is already being drawn for other diagnostic purposes.

OraQuick ADVANCE® testing is relatively expensive. Therefore, it is important to note that use of OraQuick ADVANCE® collection kits are intended to supplement rather than replace current testing methods.

OraQuick ADVANCE® may be offered as an alternative to veinipucture to encourage high-risk individuals to be tested for HIV who might otherwise not be tested at all. High-risk behaviors include: unprotected sex (anal and/or vaginal intercourse); sharing needles for drug use, tattooing or body piercing; trading sex for money and/or drugs; history of multiple sex partners etc.

Conditions for OraQuick ADVANCE® Use:

IS RAPID HIV TESTING RIGHT FOR YOUR JURISDICTION?

In most cases, health departments are likely to consider rapid HIV testing more appropriate for particular settings within an organization rather than for an organization as a whole. In general, if there are settings within your area where rates of return for test results are sub-optimal, rapid HIV testing may be a useful tool to improve these rates. Similarly, if there are communities at increased risk for HIV who are not currently availing themselves of HIV CTR services, rapid HIV testing may be one mechanism for encouraging use of these services. The CDC's *Revised Guidelines for HIV Counseling, Testing and Referral* provides technical guidance on the uses of testing technologies,

including HIV rapid tests, and should be used to help determine the benefits of a particular technology within your jurisdiction.

OraQuick ADVANCE® is a single-use qualitative, immunoassay to detect antibodies to HIV Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid, fingerstick whole blood, venipuncture whole blood, and plasma specimens. The result is visually readable in about 20 minutes. The materials contained in the master-shipping carton include a reusable test stand, client information pamphlets, specimen collection loops and package inserts. Included in the divided test pouch are one developer solution vial, one test device and one absorbent packet (See Fig. 1). The materials that will be needed but that are not included in the kits are disposable gloves, sterile lancets, a timer or watch, antiseptic wipes, sterile gauze pads, and a biohazard disposal container. Additionally, quality control kits will need to be available at each site as there are very specific methods used to run quality control checks that ensure the tests are functioning properly. **These quality control kits require refrigeration (2 to 8 degrees C, or 35.6 to 46.4 degrees F).**

Other Requirements

1. Agencies wishing to use the OraQuick ADVANCE® collection system must be funded by DHMH AIDS Administration for Counseling, Testing, and Referral services (CTR), either through a Unified Grant Award (UGA) or Memorandum of Understanding (MOU), or have received approval by DHMH AIDS Administration as a CTR reporting site.

2. HIV counselors collecting specimens with the OraQuick ADVANCE® must have attended the AIDS Administration sponsored or approved Level I HIV Counselor training, been assigned a unique 4-digit counselor number, and completed an AIDS Administration sponsored (or approved) training on the OraQuick ADVANCE® testing techniques.

3. All counseling will adhere to current CDC HIV Counseling, Testing and Referral Standards and Guidelines contained in the AIDS Administration's Counseling and Testing Services Policies and Procedures Manual.

4. Pre-test counseling and written informed consent documented on the State's form is required prior to collection of specimens for HIV testing per Code of Maryland Regulations (COMAR) 10.52.08 (HIV Testing and Counseling Procedures).

5. Each client must be informed that OraQuick ADVANCE® is a "presumptive positive" and that a confirmatory test will be needed to confirm HIV infection. There are two modes of testing - a blood test and an oral fluid test (Orasure). Both may be available on site. If only oral fluid (Orasure) testing is available, then referral to sites where blood testing is offered should be made. The following must be explained to each client where OraQuick ADVANCE® is being offered:

   a. Blood testing for HIV antibodies has been available since 1985 in the United States, and is the more widely utilized method for the diagnosis of HIV infection. It requires a needlestick to obtain the blood specimen.

b. Oral fluid testing for HIV-1 antibodies (Orasure) first gained Food and Drug Administration (FDA) approval in June 1996. A cotton pad on a stick is used to collect the specimen from inside the mouth. It does not require a needlestick.

c. Both types of testing for HIV meet stringent standards for approval by the FDA. However, the OraSure assay is intended to be used as an aid in the diagnosis of HIV-1 infection and must not be used to qualify blood donors or units of blood. Further, the following information regarding the accuracy of oral fluid testing should be noted:

1). Reduced sensitivity and specificity of testing with OraSure HIV-1 specimens compared with testing blood specimens.
2). The need for follow up testing with a blood specimen when clients have repeatedly indeterminate ELISA results using OraSure HIV-1 specimens.

d. The DHMH Laboratory will reject oral fluid specimens with regard to color. However, a minimum volume of 750 microliters of oral fluid specimen is required for laboratory testing.

e. The individual collecting an OraSure specimen should verify the expiration date (month and year) of the collection device and visually inspect it before opening for use.

The collection device must not be used if the product has expired, or the preservative liquid is discolored (i.e., other than blue), clear or not present at all prior to opening the package.

6. Quality Control (QC) Testing must be conducted for OraQuick ADVANCE®. Several factors will dictate how often controls need to be run. These are some general guidelines.
    a. It is important to test reagents, or kits, once, prior to being placed into service. This helps to alleviate a situation where an organization learns that a new lot of OraQuick ADVANCE® tests are not working on the day all of the old reagents are exhausted or expired.
    b. If a test is considered in the waived category by CLIA'88, then at least one control is required. It will be standard practice to test three controls, a HIV-1 positive (abnormal), an HIV-2 positive (abnormal) and a negative (normal) at some interval specific for each test.
    c. Since the OraQuick ADVANCE® test utilizes no testing equipment, calibration verification is not required.
    d. The initial QC tests must be done when a new kit is opened, before any patient specimens are reported. QC should also be run each shift that the test is performed, concurrently with the first patient sample of that shift.
    e. An OraQuick ADVANCE® control should be run:

- By each new operator prior to performing tests on patient specimens at the beginning of their shift.
- Whenever a new lot of OraQuick ADVANCE® tests are used for the first time.
- If there is a change in conditions of testing (e.g., new location, lighting, temperature, etc.) outside of temperature range 59-80 degrees F.
- At periodic intervals as specified in local quality assurance programs (at least one control per day).

f. Recording: QC information will always be placed in its own log sheet. Additionally, the Lot number and expiration date of the test material should be recorded on the OraQuick ADVANCE® Daily Patient Log sheet; this will facilitate "cross-checking" of the QC test with the material that was used for patient testing should it be needed. Other QC data should not be recorded on the patient log sheet.

7. Use of the Maryland HIV Counseling and Testing Report Form (DHMH 4381) is mandatory for reporting all CTR activities.

8. Use of the HIV Testing Lab Slip is not used for OraQuick ADVANCE®, but is used for confirmatory tests. If OraSure is used for a confirmatory test, the bubble indicating oral fluid specimen should be marked on the lab slip. A peel and stick numbered label should be removed from the Pretest form and affixed <u>lengthwise</u> to the specimen collection tube to positively identify it. Placing labels other than lengthwise on the tube creates problems at the lab during processing.

9. Clients will be post-test counseled per COMAR 10.52.08 and procedures specified in the CTR Policies and Procedures manual.

10. Clients with presumptive positive test results should be encouraged to have a <u>blood</u> specimen drawn for retesting. All HIV testing is voluntary, including submissions of second specimens to confirm positive test results of all initial specimens. (If blood testing is NOT available at a partner site, patients should be referred to a site that conducts blood testing. An alternative is to offer OraSure testing. However, if this tests is positive, blood will still have to be collected for further testing.

    a. The second specimen - a blood specimen - is obtained and tested to confirm the first positive result per lab protocol explained in the CTR Policies and Procedures Manual. This applies to <u>all</u> initial HIV positive test results.

    b. An indeterminate result usually requires retesting in six weeks. However, if an initial indeterminate result on an oral fluid specimen is

obtained, the individual will be asked for a blood specimen to run a second series of tests. Again, this second test is voluntary.

11. Appropriate referrals should be made during posttest counseling for all clients per CDC guidelines found in the CTR Policies and Procedures Manual and documented on the Posttest Counseling Form.

Rapid HIV Testing-OraQuick ADVANCE®

I. Introduction & Principle

The standard laboratory HIV testing algorithm used in the United States consists of screening with an enzyme immunoassay (EIA) and confirmation of repeatedly reactive EIAs using a Western Blot Test. Results are typically reported within 48 hours to 2 weeks. Nearly one fourth of the estimated 900,000 HIV-infected persons in the United States do not know their HIV status. It is because 30% of persons who tested HIV-positive during 2000 and 39% of persons who tested HIV-negative did not return for their test results or did not receive them otherwise. (HIV CT Client Record Report, 2000 U.S. Total; CDC unpublished data).

The OraQuick ADVANCE® Rapid HIV-1/HIV-2 Antibody Test is a ***Point-of-Care*** test to aid in the diagnosis of infection with HIV-1/HIV-2. This Rapid HIV test provides results with 99% accuracy in as little as 20 minutes from a finger stick blood sample. Thus providing results during the initial visit and enabling immediate counseling. Additionally, this test will be useful for pregnant women who do not know their HIV status at the time of delivery and for health care workers after accidental exposures to body fluids from infected individuals.

The OraQuick ADVANCE® rapid test utilizes a proprietary lateral flow immunoassay procedure. The plastic housing holds an assay test strip comprised of several materials that provide the matrix for the immunochromatography of the specimen and the platform for indication of the test results. The assay test strip, which can be viewed through the test device result window, contains synthetic peptides representing the HIV envelope region in the Test (T) zone and a goat anti-human IgG in the Control (C) zone immobilized onto a nitrocellulose membrane.

Oral fluid, finger-stick whole blood, venipuncture whole blood, or plasma specimen is collected and transferred into the vial of developer solution, followed by the insertion of the test device. The developer solution facilitates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it re-hydrates the protein-A gold colorimetric reagent contained in the device. As the specimen continues to migrate up the strip, it encounters the T zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The intensity of the line color is ***NOT*** directly proportional to the amount of antibody present in the specimen. Further up the assay strip, the sample will encounter the C zone. This built-in procedural control serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the test device. A reddish-purple line will appear in the C zone during the performance of all valid tests, whether or not the sample is positive or negative for antibodies to HIV-1/HIV-2.

The test results are interpreted after 20 minutes but not more than 40 minutes after the introduction of the test device into the developer solution containing the test specimen.

II. Specimen:
Oral fluid or Whole blood obtained by finger stick procedure (see **Blood Collection by Skin Puncture** procedure on page 15)

III. Materials: (Materials will be provided through the AIDS Administration)

A. Materials for obtaining whole blood by finger stick. Not supplied with kit
1.Lancet
2.Sterile gauze pad
3.Antiseptic wipe
4.Latex gloves
5.Timer/ Stop Watch capable of timing 20 to 40 minutes
6.Biohazard disposal container

B. Materials for obtaining oral specimen. Not supplied with kit.
1. Timer or watch capable of timing 20 to 40 minutes
2. Clean, disposable, absorbent workspace cover
3. Biohazard waste container

C. Materials supplied in kit:
1. Test device: A single use
2. Absorbent packet
3. Developer solution vial
4. Reusable test stands
5. Specimen collection loops
6. Subject information pamphlets
7. Package insert
8. Customer letter

D. Storage:
Store unused OraQuick ADVANCE® Rapid HIV-1/HIV-2 Antibody Tests unopened at 2º-27ºC (35-80º F). Do not open the Divided Pouch until you are ready to perform a test. If stored refrigerated, ensure that the Divided Pouch is brought to ambient temperature15º -37ºC (39°-99°F) before opening.

IV. Safety:
A. Handle specimens and materials contacting specimens as if capable of transmitting infectious agents.
B. Do not drink, eat, or smoke in areas where specimens are being handled.
C. Wear a lab coat, eye protection and disposable gloves while handling specimens.
D. Wash hands thoroughly after performing each test.
E. Dispose of gloves in a biohazard waste container after use.
F. Dispose of all test specimens and materials used in the test procedure in a biohazard waste container.

1. Lancets should be placed in a puncture-resistant container prior to disposal.
2. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121ºC. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants.
3. A solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination.

NOTE: Do not autoclave solutions that contain bleach.

For additional information on biosafety, refer to "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings".

A. Wipe all spills thoroughly with a solution of 10% bleach or other appropriate disinfectant.

V. Procedure:

A. Set up Instructions:

1. Give the client the " Subject Information" pamphlet provided with the kit before collecting specimen.
2. This test should be performed at ambient temperature (15º-37ºC, 59º- 99ºF). If the test device is not at room temperature, allow time to reach room temperature before removing the device from its wrapper. Remove the test device from its wrapper: open only those which will be used since unused devices which have been opened can not be stored.
3. Review specimen collection instructions.
4. Place the Reusable Test Stand on a flat, level surface. Use only the stand provided. Using the notched corners, tear the top of each end of the Divided Pouch containing the Test Device and Developer Solution Vial. To prevent contamination, leave the Test Device in the divided pouch until needed.
5. **DO NOT** touch the flat pad.
6. Check to see if an Absorbent Packet is present in the pouch with the test device. If no Absorbent Packet is present, discard the Test Device and obtain a new Divided Pouch for testing.
7. Remove the Developer Solution Vial from the Divided Pouch. Firmly holding the Developer Solution Vial, carefully uncap the vial by gently rocking the cap back and forth. Slide the uncapped Developer Solution Vial into the top of the slot in the angled Reusable Test Stand, making sure the vial is completely seated in the stand.
8. **DO NOT** force the vial into the stand from the front of the slot, as splashing may occur.

B. Oral Fluid Testing Procedure **:**

1. If tests are performed on more than one client at one time label the developer vial either with the sticker or sharpie pen appropriately.
2. Have the person being tested remove the Device from its Pouch.
3. Direct the person to place the Flat Pad above the teeth against the outer

gum. Direct the person to gently swab completely around the outer gums, both upper and lower, one time around, using the Flat Pad. **DO NOT** allow the person to swab the roof of the mouth, the inside of the cheek or the tongue. Note: Both sides of the Flat Pad may be used during this procedure.

4. Instruct the person being tested to insert the Flat Pad of the Device all the way into the Vial. Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you.
5. Start timing the test. **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops. Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.

C Fingerstick Whole Blood Testing Procedure

1. Perform skin puncture procedure of the third or fourth finger as per procedure. Wipe away the first drop of blood with a sterile gauze pad. Touch the round end of an unused Specimen Collection Loop to the next drop of blood from the puncture site. Visually inspect the loop to make sure that it is completely filled with blood.
2. Immediately immerse the blood-filled Specimen Collection Loop in the developer solution inside the Developer Solution Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Solution Vial and discard the used loop in a biohazard waste container.
3. Examine the solution in the Developer Solution Vial to ensure that it appears pink, indicating that the blood specimen was properly introduced. If the developer solution is not pink after adding the specimen, discard the Developer Solution Vial as infectious waste, open a new Divided Pouch, and collect a new specimen.
4. Remove the Test Device from the Divided Pouch without touching the flat pad. Insert the Test Device, flat pad first, into the Developer Solution Vial containing the specimen. **Be sure that the result window faces forward and the flat pad touches the bottom of the Developer Solution Vial**.
5. **DO NOT** cover the two holes in the back of the Test Device either before or after placing it into the developer solution. Doing so may cause an invalid result
6. Leave the Test Device in the Developer Solution Vial and start a timer. **Do not remove the Test Device from the vial until you have read the results**. Read the results after at least 20 minutes but not more than 40 minutes later in a well-lighted area.
7. Read the results: Note whether there is a band opposite the “C” and “T” area.
8. After recording the results, dispose of the used Developer Solution Vial and the Test Device in a biohazard waste container.
9. Follow CDC guidelines to inform the test subject of the test result and its interpretation.

C. Reading the Test

1. Sample of a **Non-Reactive** (negative) Result: (see figure below)
   - Only the control (C) area shows a line.
   - No line is present in the test (T) area.
   - Test result interpreted as **NEGATIVE FOR HIV-1/HIV-2 Antibodies**.

Figure 1

2. Sample of a **Reactive** (positive) Result: (see figures below)
   - Lines appear in <u>both</u> the control (C) and the test (T) areas.
   - Reactive results **must** be confirmed.
   - Test result interpreted as **PRELIMINARY POSITIVE FOR HIV-1 AND/OR HIV-2 Antibodies**

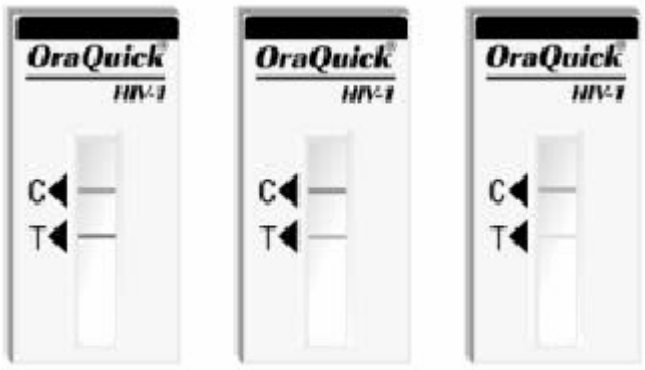


Figure 2

3. Sample of **Invalid** Result: (see figures below)
   - **No line** is present in the area adjacent to either the "C" or "T" triangle
   - A line appears opposite the "T" triangle but not the "C" triangle
   - A red background in the result window makes it difficult to read the results after 20 minutes
   - A line appears, but not opposite the "C" (or "T") triangle - misalignment

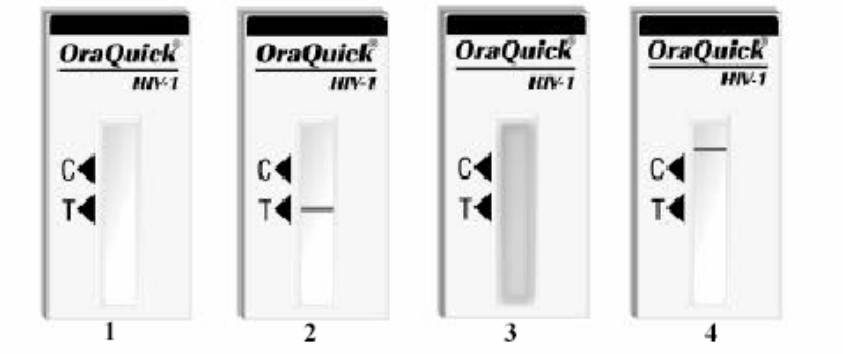


Figure 3

D. <u>Clinical Results Interpretation:</u>
   1. **Non-Reactive** (Negative): These individuals are not currently infected. Exceptions include those who have had a recent (within 3 months) known or a possible exposure to HIV or are in the process of seroconversion. . Recommend a retest for these clients.
   2. **Reactive** (Preliminary Positive) Test: Further testing is always required to confirm a reactive screening test result. Convey this information like this: *"Your preliminary test result was positive, but we won't know for sure if*

you are HIV-infected until we get the results from your confirmatory test". The client must be instructed to avoid transmission of virus. It is essential to explain:

- The meaning of reactive screening test result in simple terms, avoiding technical jargon.
- Emphasize the importance of confirmatory testing and obtain a 2nd sample immediately or schedule a return visit for confirmatory test results.
- Underscore the importance of taking precautions to prevent transmitting infection to others while awaiting results of confirmatory testing.

VI. Quality Control

A. Controls:

Each kit control box contains a package insert and three vials: One HIV-1 positive, one HIV-2 positive, and one negative control (human plasma based reagents). These kit controls verify that the test is working properly. These are negative for Hepatitis B and Hepatitis C antibody.

B. Frequency of Controls:

1. Commercial positive and negative controls will be checked with:
   - Each new lot of test packs prior to placing them in service.
   - With change of every new operator prior to performing testing on patient specimens introduced for testing.
   - If there is a change in the conditions of testing (e.g. new location, lighting, temperature, etc.).
   - Once per day/shift on which the test is performed.

C. Use:

Store the OraQuick ADVANCE® Test Kit Controls at 2-8^0 C (36.6 – 46.4 F). Do not use controls past the expiration date printed on the outer carton. Open control vials only when you are performing tests. Recap and store the vials in their original container at 2-8^0 C after use. Opened vials expire 21 days after they are put in use. Do not use controls if the reagent appears visually cloudy or discolored. Bring control vials to room temperature before use.

D. Expected Values:

1. Positive control: both the control "C area" region and test "T area" region will show a line. (see Figure 2)
2. Negative control: only the control "C area" region will turn color, the test "T area" region will not show a line. (see Figure 1)

E. Quality Control Records:

Quality Control (QC) information is to be recorded on the appropriate QC Log Sheet (see attachments). The information required includes name of test (pre-printed on sheet), site where test was performed, date, time name of person performing the test, lot numbers of all reagents, expiration dates of all reagents, expected results and observed results

F. Corrective Action:

1. If the controls fail to yield the expected results, **DO NOT** perform any patient testing until performance issues are resolved and expected results are obtained and recorded.
2. Document the corrective action taken; see the Quality Assurance manual and Corrective Action Guidelines.

VII. Limitation of Method:

A. The OraQuick ADVANCE® Rapid HIV-1/HIV-2 Antibody Test must be used in accordance with the instructions in the package insert for the device to obtain an accurate result.

B. FDA and CDC classify this procedure as a CLIA waived procedure. However, the procedure must only be performed by persons who have received appropriate training and their competency documented.

C. Reading test results earlier than 20 minutes or later than 40 minutes may yield erroneous results.

D. FDA approves this test for use with oral fluid, finger-stick whole blood specimens, venipuncture whole blood, and plasma specimens. Use of other types of specimens may not yield accurate results. Clinical data has not been collected to demonstrate the performance of the OraQuick ADVANCE® Rapid HIV-1/HIV-2 in persons under age of 13.

E. A Reactive result using the OraQuick ® ADVANCE® Rapid HIV-1/HIV-2 Antibody Test suggests the presence of anti-HIV-1 and/or HIV-2 antibodies in the specimen. The OraQuick ADVANCE® Rapid HIV-1/HIV-2 Antibody Test is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.

F. For a Reactive result, the intensity of the test line does not necessarily correlate with the amount of antibody in the specimen.

G. When an insufficient amount of blood has been added to the test device, the control band will not appear on the membrane. An additional prick may be required and use a new device. If the control band still fails to appear, the test should be terminated since deterioration of the test device may have occurred. Report the matter to the laboratory director.

H. A Non-Reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels. Rule out a history of exposure to HIV within 3 months. Recommend a retest for clients with a recent exposure.

Obtaining OraQuick ADVANCE® testing Devices:

OraQuick ADVANCE® collection devices will be ordered through a Master Purchase Agreement held by the AIDS Administration. Distribution will be the responsibility of the AIDS Administration. All agencies must be approved by DHMH, AIDS Administration to obtain collection devices through this agreement. Provision of OraQuick ADVANCE® collection devices and Control Kits is contingent upon receipt of federal funding and cannot be guaranteed.

OraQuick ADVANCE® test kits will be distributed through the AIDS Administration from our Distribution Center the same way OraSure has been distributed. Since control kits need refrigeration, and their use will vary according to the amount of tests performed and the environmental changes of the testing site, control kits will be shipped directly to organizations from the manufacturer. These kits also will be ordered through the AIDS Administration.

To obtain collection devices and control kits, along with other lab equipment, agency representatives should contact the Jenny Bolster, RN, MS, CIC, Rob Lunn, MPA, Jenna McCall MPH, Dana Herrod, or Rob Marino at the AIDS Administration, DHMH, 500 N. Calvert Street, 5th Floor, Baltimore, MD 21202. Telephone (410) 767-5018. The following information must be provided:

a. agency or organization making the request;
b. number of collection devices or control kits required;
c. name and telephone number of contact person to receive the product;
d. address where devices are to be shipped. (Cannot be a PO Box).

Agencies may be notified of actions which will ensure compliance with all conditions for use of OraQuick ADVANCE® by staff in their organization. This may require submission of a written proposal for DHMH approval as a "designated anonymous testing site", or approval for provision of "confidential HIV Counseling, Testing, and Referral (CTR)."

Oral Fluid Specimen Collection

I. Purpose:

To obtain oral fluid for HIV-1/HIV-2 testing by swabbing the mouth

II. Materials and Equipment:

A. Clean, absorbent workspace cover
B. OraQuick reusable test stand
C. OraQuick ADVANCE® Kit

III. Procedure

A. Have the person being tested remove the device from its pouch.
B. DO NOT allow the person to touch the flat pad.
C. Check to make sure that an absorbent packet is included with the device. If no absorbent packet is present, discard the device and obtain a new pouch for testing.
D. Direct the person the place the flat pad above the teeth against the outer gum. Direct the person to gently swab completely around the outer gums, both upper and lower, one time around, using the flat pad. DO NOT allow the person to swab the roof of the mouth, the inside of the cheek, or the tongue. NOTE: Both sides of the flat pad may be used.

Blood Collection by Skin Puncture
for Adult Patients

I. Purpose:

To obtain an adequate blood for laboratory tests through a skin puncture.

IV. Materials And Equipment:

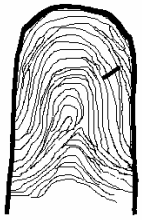
A. Disposable latex gloves (or non-latex if employee and/or patient has a latex allergy).
B. Isopropyl alcohol
C. Cotton balls or gauze
D. Blood lancets for skin puncture
E. Sharp's containers
F. Band Aids (optional)
G. Appropriate microcuvettes, or tubes for micro sampling
H. Disinfectant (10% household bleach) for bench tops

V. Safety:

A. Use universal precautions as outlined in the Bloodborne Pathogen Plan.
B. Place sharp's container close to the collection site.
C. Wear disposable gloves, and lab coat (for pediatric and uncooperative patients) at all times during the procedure.
D. Change gloves between patients.

VI. **Procedure**:

A. The procedure should be explained to the patient, and parent or guardian.
B. According to the NCCLS document, "Recommendations for Puncture Sites for Whole Blood Samples" the third or fourth (middle or ring) finger is used to obtain a sample. Choose a site that is on the side of the fingertip, midway between the edge and midpoint of the fingertip. Have client thoroughly wash hands with warm soapy water.



C. Thoroughly cleanse the chosen site with 70% alcohol. Wipe excess alcohol with sterile gauze. Allow the skin to air-dry. Wet alcohol remaining on the skin will sting the client and may dilute the sample.

D. Use a sterile, OSHA approved, blood lancet to make a deep puncture (1.5 mm) at the chosen site. (A deep puncture is no more painful that a superficial one, gives a much better flow, and makes it unnecessary to repeat the procedure.) Immediately dispose of contaminated lancet into a sharp's container.

E. Using a dry gauze, wipe away the first drop of blood, making certain the area is completely dry.

F. Apply moderate pressure, approximately 1 cm behind the site of the puncture to obtain a drop of blood.

G. Release this pressure immediately to allow recirculation of the blood.

H. Repeat steps F & G until enough blood has been collected.

I. Apply a piece of gauze, (or cotton ball), to the puncture site, using slight pressure until the bleeding has stopped. Offer patient a band-aid.

V. References:

A. NCCLS. Volume 2. No. 5. "Approved Standard Procedures for the Collection of Diagnostic Blood Specimen by Skin Puncture". 1982.

B. Brown, Barbara, 1980. Hematology: Principles and Procedures. Third Edition. Lea & Febiger. Philadelphia, PA.

Standard Laboratory Procedure and Overview

I. Introduction:

Clinical laboratory testing is a managed art. It has developed over time with increasing regulation on one hand and increasing professional standards through peer review on the other. With the 1988 amendments of the Federal Clinical Laboratory Improvement Act, all clinical testing sites are now required to be certified by US HCFA. In some cases, this will mean actual on site inspection to see that mandated procedures are followed. For professional clinical laboratories that have been in business for some time, this is nothing new. For small testing facilities such as the doctor's office and the public health clinic, the additional regulation may appear as an impossible burden. What CLIA'88 actually requires is that any site, which performs clinical diagnostic testing, will adhere to a good laboratory practice standard.

The regionalization of local public health facilities which perform clinical laboratory tests has been a direct response to the CLIA=88 legislation. Regional management is a large cooperative undertaking for DHMH and local public health departments.

The CLIA'88 legislation established three categories of clinical laboratory testing; waived, moderately complex and complex. The majority of tests in public health fall into waived category with the remainder in the moderately complex category. In Maryland, public health testing is **not** waived and is considered of high complexity. The primary regulatory distinction between these two categories is whether proficiency testing and on-site inspections are required. In general, each local health department has adequate trained personnel to meet the criteria required to perform the proper complex category. The actual procedural documentation, and quality control testing requirements are much the same for both categories. Those tests which fall in the waived category will be "inspected" by the laboratory director and they will be checked with an internal proficiency test rather than an external proficiency test. Otherwise, the same policies and standards will be applied throughout. This approach will assure consistency in test performance and quality control on a statewide basis, and thus defines the standard of laboratory practice.

Please note: Further modules of this manual are under development and will be incorporated as they are finalized. You will be issued the updates as they become available.

II. Administrative Issues:

A. Each local health department will have one or more "site coordinators" who will be senior clinical administrators with an RN or BS degree.

B. This section is a brief outline of the duties, which are explained further in the Quality Assurance Manual. The **Site Coordinator** is the key to the effectiveness of the Regional Laboratory System at the local level and will be responsible for following activities:

1. Maintaining personnel lists of people performing testing, including which staff members perform which types of test(s). Whenever this list changes, a

copy will be sent to the lab director. This information is to be recorded in the Organizational Structure and HCFA209 documents (see QA Manual Appendix)

2. Maintaining a list of tests being performed, and the location of the testing facility. If the test is performed off site at a variety of different sites, the home site should be listed. This information is recorded in the Organizational Structure Document
3. Maintaining records of personnel training and competency evaluation for clinical tests may be required. Refer to the guidelines on Competency and Proficiency Testing.
4. Maintaining a file of completed quality control records and corrective actions. Refer to the Quality Assurance Manual.
5. Maintaining copies of test procedures (the procedure manual), including active procedures currently in use, and discontinued procedures for two years.
6. Maintaining copies of any proficiency test results, either internal or external. Refer to the Proficiency Testing Guidelines and Quality Assurance Manual.
7. Assigning someone to be in charge of writing new procedures and reviewing them on an ongoing basis for any method or reagent changes. This task should be assigned to someone who actually performs the test or procedure in question. (See "Test Procedures" in following a section) All procedures must be reviewed and approved by the Technical Consultant or Laboratory Director before they are placed in service.
8. Reviewing and posting changes in Administrative, Quality Assurance and Procedure Manuals. After posting, will insure that testing personnel are aware of new procedures and changes in older procedures.

C. Accreditation Issues:

1. Maryland DHMH and Health Care Quality manages and implements the accreditation program for local public health in Maryland. For each area, the accreditation document lists <u>minimum</u> criteria. This means that a site has to have more than just generic forms and procedures in place, it must go beyond the accreditation document to satisfy the "sprit of the law" on which the document is based. Each site is individually responsible to evaluate the criteria and insure that they have fully met the intention of the criteria. Strictly speaking, this is not a laboratory issue, but the Laboratory Director may provide consultation and oversight in the development of guidelines for specific sites. For example, having a generic Blood Borne Safety Plan that is does not specifically address the hazards at your site, or is never reviewed, or presented to the staff on an annual basis does not fulfill the criteria.

2. A Chemical Hygiene Plan and a Blood Borne Pathogens Plan, are required by both OSHA, MOSHA. While the Chemical Hygiene Plan is not a CLIA issue, the Blood Borne Pathogen Plan is. Both plans must <u>specifically</u> address your site: generic documents provided as part of the regional laboratory system must be "customized" for your specific health jurisdiction. The Chemical Hygiene Plan needs to address Material Safety Data Sheets (MSDSs), where and how they are filed and how they are reviewed; they must be made available to all staff at any time. Both management and staff

must review these plans at least annually. Training on both plans for the staff must be conducted on an annual basis with evidence of attendance by appropriate staff.

D. Corrective Action (as specifically applicable for your organization):
1. Whenever equipment or quality control checks fail, the corrective action taken to rectify the situation should be documented. Commonly this can be done on the QC log for the procedure in question. If it is more involved, the appropriate form for the situation must be completed and sent to the Laboratory Director from the Site Coordinator. The corrective action report should specifically address who was performing the testing, when the failure or problem occurred, where the problem happened, what was wrong and what was done about it. The corrective action should specifically note whether clients were tested with faulty equipment or reagents.
2. Whenever an error or problem results in faulty communication of laboratory results, or there is an inquiry or complaint, the incident must be documented. The documentation should indicate the problem, personnel involved, and final resolution. A simple log sheet for "Laboratory Communication Problems" is adequate for minor situations. As before, if more documentation is needed, take the time and effort to completely document the problem and its resolution on a Communications Complaint Report.

III. Competency Testing (CT)

The CLIA '88 legislation requires a mechanism to evaluate and demonstrate competency in test performance for each person who performs a clinical diagnostic test. This means that the Laboratory Director, Technical Consultant, Site Coordinator, or other designated person must critically observe the individual being evaluated to determine that procedural methods and protocols are followed correctly, technique is adequate and safety guidelines are followed. While a summary follows, please refer to the Competency Evaluation guideline for extensive details.

A. Competency Evaluation must be performed according to the following schedules;
1. New personnel must demonstrate competency in performing each test procedure prior to reporting patient results.
2. New personnel must demonstrate competency in performing each test procedure twice during the first year in which they begin to perform the procedure.
3. After the first year of employment, each person must demonstrate test proficiency on an annual basis.
4. If a new test method is added, or existing procedures substantially changed, all testing personnel must demonstrate competency in performing the new (or altered) test procedure.

IV. Proficiency Testing (PT)

While a summary of proficiency testing follows, please refer to the Guidelines for

External Proficiency Testing and Internal Proficiency Testing for extensive details.

A. External proficiency testing is required for all tests which fall in the moderately complex category according to CLIA'88. Since this may be performed at any site under one CLIA registration number, external proficiency testing will be rotated. An exception to this will be: if one site performs a moderately complex test which is not performed by other sites within that region, they must acquire and pay for a separate external proficiency program for the special procedure they perform. External proficiency programs are national in scope; identical material is shipped to every laboratory enrolled. It will be the responsibility of the Laboratory Director to order and arrange payment for the designated proficiency test. The Laboratory Director must review and approve the results of all external proficiency tests.

B. Internal proficiency, if utilized, is testing designed to demonstrate that each laboratory site would yield the same test result for a given sample. Unknown samples should be utilized twice a year for proficiency testing; each set will contain five samples for each moderately complex test and three samples for each waived test. Internal proficiency testing will be applied to all tests regardless of category. The results will **be filed in a Proficiency Test Result file or folder** for retrieval and review**,** and a copy will be sent to the Laboratory Director within the specified time frame. The correct results will be mailed to each site which submitted a report, and it too should be filed with the quality control logs.

C. In all proficiency test programs, the sample should be tested as if it were just another clinical sample. The person performing the test must sign and date the report.

D. Results of proficiency tests must be reviewed, signed and dated by the person who performed the test, site supervisor, and the laboratory director. Any corrective action, including training, must be described in writing, dated and signed before filing with the proficiency test results. This should not be considered a disciplinary action, it should be considered an educational and quality assurance activity.

V. Manuals and Written Documents

There are several documents each laboratory site should have which will be written by site personnel. The format will adhere to standards set by the National Committee for Clinical Laboratory Standards (NCCLS), The American Society for Microbiology (ASM), and the American Association of Bioanalysts (AAB). The NCCLS approved standards will be the primary standard. While adherence to these standards is not specifically required by Health Education and Welfare (HEW), they exceed and are completely accepted by HEW and HCFA for regulatory purposes.

The required documents can be grouped into the following classes which will be bound together to form operating manuals. In many cases, guidelines may have to be modified to address specific issues at each site.

A. Administrative documents - **Administrative Manual**

1. Administrative structure, personnel names, duties, and locations. There are two forms, which document this information, the Organizational Structure and the HCFA209 for supervisory and moderately complex testing personnel and the 209b for waived testing personnel.
2. Daily Logs & Worksheets - often bound separately
3. Employee Orientation, Training & Competency Review and associated forms.
4. Hazardous Waste Policy - specific for the laboratory site. This may be located in the Chemical Hygiene Plan
5. Specimen Acceptance, Accessioning & Handling, especially for those specimens that are sent to testing facilities out side of your health department.
6. Preventative Maintenance Program
7. Protocol for Extreme Test Results
8. Quality Assurance Plan - specific for the laboratory site and sometimes in a separate binder.
9. Universal Precautions & Blood Borne Pathogens - specific for the laboratory site and often part of your Safety Manual.

B. Technical Testing Procedures - **Procedure Manual**

Every test must have a written procedure, even if the test came with a complete printed manual. A manufacturer's manual is so complete that a secondary written procedure only needs to address those matters that are specific to the operating site and reflect regional laboratory policy.

C. Revision or replacement of documents;

1. Whenever a policy or procedure is removed or replaced, the new document must reference the earlier document. Quality Control Records and Patient Logs are also kept filed for one (1) year.

2. Interim revisions are allowed, but they must be;
   a. written very clearly and in ink or typed; lead pencils are <u>not</u> acceptable
   b. signed or initialed
   c. dated
   d. It is **essential** that revisions are uniform through out the region and are done with the full knowledge and approval of the Laboratory Director or Technical Coordinator.

VI. Review:

Each guideline and procedure should be reviewed by Site Coordinator and other personnel once a year. The site coordinator may review the manuals, at the direction of the Technical Consultant or Laboratory Director, if there have been <u>no changes</u> in the document other than minor interim revisions.

MODEL EXPOSURE CONTROL PLAN

The following Model Exposure Control Plan is intended to serve employers as an example of an exposure control plan which is required by the Bloodborne Pathogens Standard. A central component of the requirements of the standard is the development of an exposure control plan (ECP).

The intent of this model is to provide small employers with an easy-to-use format for developing
a written exposure control plan. **Employers will need to adjust or adapt the model for their specific use.**

The information contained in this publication is not considered a substitute for the OSH Act or
any provisions of OSHA standards. It provides general guidance on a particular standard-related
topic but should not be considered a definitive interpretation for compliance with OSHA requirements. The reader should consult the OSHA standard in its entirety for specific compliance requirements.

BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

Local Health Department (Name)

DATE (Month, day, year)

POLICY

The *(Facility Name)* is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance
with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

The ECP is a key document to assist our firm in implementing and ensuring compliance with the
standard, thereby protecting our employees. This ECP includes:

* Determination of employee exposure
* Implementation of various methods of exposure control, including:

    Universal precautions
    Engineering and work practice controls
    Personal protective equipment
    Housekeeping

* Hepatitis B vaccination
* Post-exposure evaluation and follow-up

* Communication of hazards to employees and training
* Record keeping
* Procedures for evaluating circumstances surrounding an exposure incident
*The methods of implementation of these elements of the standard are discussed in the subsequent pages of this ECP.

PROGRAM ADMINISTRATION

*_(*Name of responsible person or department*)_____ is (are) responsible for the implementation of the ECP. _(*Name of responsible person or department*)_____ will maintain, review, and update the ECP at least annually, and whenever necessary to include new or modified tasks and procedures. Contact location/phone number:_____

* Those employees who are determined to have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with the procedures and work practices outlined in this ECP.

* ___(*Name of responsible person or department*)_____ will maintain and provide all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags as required by the standard. __(*Name of responsible person or departmen*t_____ will ensure that adequate supplies of the aforementioned equipment are available in the appropriate sizes. Contact location/phone number:_____

*_(*Name of responsible person or department*)_____ will be responsible for ensuring that all medical actions required are performed and that appropriate employee health and OSHA records are maintained. Contact location/phone number:_____

*_(*Name of responsible person or department*)_____ will be responsible for training, documentation of training, and making the written ECP available to employees, OSHA, and NIOSH representatives. Contact location/phone number:_____

EMPLOYEE EXPOSURE DETERMINATION

The following is a list of all job classifications at our establishment in which **all** employees have
occupational exposure:

JOB TITLE DEPARTMENT/LOCATION
(Example: Phlebotomists) (Clinical Lab)

_____ _____

_____ _____

_____ _____

_____ _____

The following is a list of job classifications in which **some** employees at our establishment have
occupational exposure. Included is a list of tasks and procedures, or groups of closely related
tasks and procedures, in which occupational exposure may occur for these individuals:

JOB TITLE DEPARTMENT/LOCATION TASK/PROCEDURE
(Example: Housekeeper - Environmental Services - Handling Regulated Waste)

_____ _____
_____

Part-time, temporary, contract and per diem employees are covered by the standard. How the
*provisions of the standard will be met for these employees should be described in the EC*P.

METHODS OF IMPLEMENTATION AND CONTROL

Universal Precautions

All employees will utilize universal precautions.

Exposure Control Plan

Employees covered by the bloodborne pathogens standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training. All employees have an opportunity to review this plan at any time during their work shifts by contacting _(*Name of responsible person or department*)_____. If requested, we will provide an employee with a copy of the ECP free of charge and within 15 days of the request. ___(*Name of responsible person or department*)_____ is responsible for reviewing and updating the ECP annually or more frequently if necessary to reflect any new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

Engineering Controls and Work Practices

Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. The specific engineering controls and work practice controls used are listed below:

* _*(For example: non-glass capillary tubes, SESIPs, needleless systems)*
* _____
* _____

Sharps disposal containers are inspected and maintained or replaced by ___(*Name of responsible person or department*)_____ every ___*(list frequency*_____ or whenever necessary to prevent overfilling.

This facility identifies the need for changes in engineering control and work practices through *(Examples: Review of OSHA records, employee interviews, committee activities, etc.)*

We evaluate new procedures or new products regularly by *(Describe the process, literature reviewed, supplier info, products considered)*

_____
_____

Both front line workers and management officials are involved in this process: *(Describe how employees will be involved)*

(Name of responsible person or department) will ensure effective implementation of these recommendations.

Personal Protective Equipment (PPE)

PPE is provided to our employees at no cost to them. Training is provided by __(*Name of responsible person or department*)_____ in the use of the appropriate PPE for the tasks or procedures employees will perform.

The types of PPE available to employees are as follows:

__*(Ex., gloves, eye protection, etc*.)_____

PPE is located ____*(List location*)_____ and may be obtained through_*(Name of responsible person or department*)_____ (Specify how employees are to obtain PPE, and who is responsible for ensuring that it is available.)

All employees using PPE must observe the following precautions:

* Wash hands immediately or as soon as feasible after removal of gloves or other PPE.
* Remove PPE after it becomes contaminated, and before leaving the work area.
* Used PPE may be disposed of in _____(List appropriate containers for storage, laundering, decontamination, or disposal.)

* Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminatedD-6 items or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.
* Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
* Never wash or decontaminate disposable gloves for reuse.

* Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.
* Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

The procedure for handling used PPE is as follows: *(may refer to specific agency procedure by title or number and last date of review)*

_____
_____

(For example, how and where to decontaminate face shields, eye protection, resuscitation equipment)

Housekeeping

Regulated waste is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded (see Labels), and closed prior to removal to prevent spillage or protrusion of contents during handling.

The procedure for handling **sharps disposal containers** is: *(may refer to specific agency procedure by title or number and last date of review)*

_____
_____

The procedure for handling **other regulated waste** is: *(may refer to specific agency procedure by title or number and last date of review)*

_____
_____

Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and labeled or color-coded appropriately. Sharps disposal containers are available at _____(*must be easily accessible and as close as feasible to the immediate area where sharps are use*d).

Bins and pails (e.g., wash or emesis basins) are cleaned and decontaminated as soon as feasible after visible contamination.

Broken glassware which may be contaminated is picked up using mechanical means, such as a brush and dustpan.

Laundry

The following contaminated articles will be laundered by this company:

_____ _____
_____ _____

Laundering will be performed by _*(Name of responsible person or department)*
_____ at *(time and/or locatio*n) .

The following laundering requirements must be met:

* handle contaminated laundry as little as possible, with minimal agitation
* place wet contaminated laundry in leak-proof, labeled or color-coded containers before transport. Use *(red bags or bags marked with biohazard symbo*l)_____ for this purpose.
* wear the following PPE when handling and/or sorting contaminated laundry: *(List appropriate PP*E)_____

Labels

The following labeling method(s) is used in this facility:

EQUIPMENT TO BE LABELED LABEL TYPE (size, color, etc.)
(e.g., specimens, contaminated laundry, etc.)(_red bag, biohazard label, etc.)
_____ _____
_____ _____

__*(Name of responsible person or department*)_____ will ensure warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Employees are to notify _____ if they discover regulated waste containers, refrigerators containing blood or OPIM, contaminated equipment, etc. without proper labels.

Equipment, Environment and Work Surfaces

1. Contaminated work surfaces shall be decontaminated with an appropriate disinfectant:

    a. After completion of procedures;

    b. Immediately or as soon as feasible when surfaces are clearly contaminated or after any spill of blood or other potentially infectious materials

    c. At the end of the work shift, if the surface may have become contaminated since the last routine cleaning.

2. Spills of blood should be decontaminated with freshly diluted (1:10) bleach, or with an EPA – approved disinfectant. Appropriate gloves, gowns and masks should be worn if necessary to protect clothing and employee during cleaning and decontamination procedures. Cover spill with paper towels or other absorbent material and flood with diluted bleach solution. Let stand for at least 10 minutes.

Clean up with more paper towels. Dispose of as infectious waste. With large spills of culture or concentrated infectious agents in the laboratory, the contaminated area should be flooded with a liquid germicide before cleaning, then decontaminated with fresh germicidal chemical.

3. Protective coverings, such as plastic wrap, aluminum foil or imperviously- backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible, when they become openly contaminated or at the end of the workshift if they "may" have become contaminated.

4. Broken glassware, which may be contaminated, should not be picked up directly with the hands. It must be soaked with disinfectant and then cleaned up using mechanical means, such as a brush and dustpan, tongs or forceps.

HEPATITIS B VACCINATION

(Name of responsible person or department)_____ will provide training to employees on hepatitis B vaccinations, addressing the safety, benefits, efficacy, methods of administration, and availability.

The hepatitis B vaccination series is available at no cost after training and within 10 days of initial assignment to employees identified in the exposure determination section of this plan. Vaccination is encouraged unless: 1) documentation exists that the employee has previously received the series, 2) antibody testing reveals that the employee is immune, or 3) medical evaluation shows that vaccination is contraindicated.

However, if an employee chooses to decline vaccination, the employee must sign a declination form. Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the vaccination is kept at _____*(List location or person responsible for this record keeping).*

Vaccination will be provided by _(List *Health care Professional who is responsible for this part of the pla*n) at *(location)* .

Following the medical evaluation, a copy of the health care professional's Written Opinion will be obtained and provided to the employee. It will be limited to whether the employee requires the hepatitis vaccine, and whether the vaccine was administered.

POST-EXPOSURE EVALUATION AND FOLLOW-UP

Should an exposure incident occur, contact ____*(Name of responsible person)* at the following number:_____.

An immediately available confidential medical evaluation and follow-up will be conducted by *(Licensed health care professional)* . Following the initial first aid (clean the wound, flush eyes or other mucous membrane, etc.), the following activities will be performed:

* Document the routes of exposure and how the exposure occurred.
* Identify and document the source individual (unless the employer can establish that identification is infeasible or prohibited by state or local law).
* Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual's test results were conveyed to the employee's health care provider.
* If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.
* Assure that the exposed employee is provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
* After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status * If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90 days; if the exposed employee elects to have the baseline sample tested during this
waiting period, perform testing as soon as feasible.

ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

(Name of responsible person or department)_____ ensures that health care professional(s) responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up are given a copy of OSHA's bloodborne pathogens standard.

___*(Name of responsible person or department*)_____ ensures that the health
care professional evaluating an employee after an exposure incident receives the following:

* a description of the employee's job duties relevant to the exposure incident
* route(s) of exposure
* circumstances of exposure
* if possible, results of the source individual's blood test
* relevant employee medical records, including vaccination status

__*(Name of responsible person or department*)_____ provides the employee with a copy of the evaluating health care professional's written opinion within 15 days after completion of the evaluation.

PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AN EXPOSURE INCIDENT

(Name of responsible person or department)_____ will review the circumstances of all exposure incidents to determine:
* engineering controls in use at the time
* work practices followed
* a description of the device being used (including type and brand)
* protective equipment or clothing that was used at the time of the exposure incident *(gloves, eye shields, etc.)*
* location of the incident *(O.R., E.R., patient room, etc.)*
* procedure being performed when the incident occurred
* employee's training

(Name of Responsible Person) will record all percutaneous injuries from contaminated sharps in the Sharps Injury Log.

If it is determined that revisions need to be made, __*(Responsible person or department*)_____ will ensure that appropriate changes are made to this ECP. *(Changes may include an evaluation of safer devices, adding employees to the exposure determination list, etc.)*

EMPLOYEE TRAINING

All employees who have occupational exposure to bloodborne pathogens receive training conducted by *(Name of responsible person or department) . (Attach a brief description of their qualifications.)*

All employees who have occupational exposure to bloodborne pathogens receive training on the
epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the
training program covers, at a minimum, the following elements:

* a copy and explanation of the standard
* an explanation of our ECP and how to obtain a copy
* an explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident
* an explanation of the use and limitations of engineering controls, work practices, and PPE
* an explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE
* an explanation of the basis for PPE selection

* information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge
* information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM

* an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available
* information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
* an explanation of the signs and labels and/or color coding required by the standard and used at this facility
* an opportunity for interactive questions and answers with the person conducting the training session.

Training materials for this facility are available at _____.

RECORDKEEPING

Training Records

Training records are completed for each employee upon completion of training. These documents will be kept for at least **three years** at __*(Name of responsible person or location of records*)_____.

The training records include:

* the dates of the training sessions
* the contents or a summary of the training sessions
* the names and qualifications of persons conducting the training
* the names and job titles of all persons attending the training sessions

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to ___*(Name of Responsible person or Department*)_____

Medical Records

Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records."

(Name of Responsible person or department) is responsible for maintenance of the required medical records. These **confidential** records are kept at ____*(List location*)_____for at least the **duration of employment plus 30 year**s.

Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be

sent to ____*(Name of responsible person or department and address*)_____

OSHA Record keeping

An exposure incident is evaluated to determine if the case meets OSHA's Record keeping Requirements (29 CFR 1904). This determination and the recording activities are done by _*(Name of responsible person or department*)_____.

Sharps Injury Log

In addition to the 1904 Record keeping Requirements, all percutaneous injuries from contaminated sharps are also recorded in the Sharps Injury Log. All incidences must include at least:
- the date of the injury
- the type and brand of the device involved
- the department or work area where the incident occurred
-an explanation of how the incident occurred.

This log is reviewed at least annually as part of the annual evaluation of the program and is maintained for at least five years following the end of the calendar year that they cover. If a copy is requested by anyone, it must have any personal identifiers removed from the report.

HEPATITIS B VACCINE DECLINATION (MANDATORY)

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Signed:__(*Employee Name*)_____

Date:_____

This Bloodborne Pathogens Hazard Communication Plan has been reviewed and approved for use without modification. The facilities and precautions are compatible with current knowledge and regulations at this time:

Review
Date/Signature_____

Review
Date/Signature_____

Review
Date/Signature_____

Review
Date/Signature_____
_

FORMS

The following pages include various forms that can be adapted and used by your agency in your OraQuick ADVANCE® program.